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Application Number	09/808,314
Filing Date	March 14, 2001
First Named Inventor	Randall W. Nelson
Art Unit	1641
Examiner Name	Gary W. Counts
Attorney Docket Number	41821.0238

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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- ☐ After Allowance Communication to TC
- ☑ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Date	March 24, 2008	Reg. No.	36,078

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Signature	Laura J. Zeman		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Randall W. Nelson et al.
Serial No.:	09/808,314
Filing Date:	March 14, 2001
Title:	MASS SPECTROMETRIC IMMUNOASSAY
Examiner:	Gary W. Counts
Art Unit:	1641

TO: Mail Stop APPEAL BRIEF-PATENTS
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REQUEST FOR REHEARING PURSUANT TO 37 CFR §41.52

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(Submitted in Triplicate)

The Board of Patent Appeals and Interferences issued a Decision on Appeal regarding Appellant's patent application having Serial No. 09/808,314 on January 24, 2008. Pursuant to 37 CFR § 41.52, Appellant timely requests a rehearing on the patentability of claims 31-48 contained in the appeal.

Appellant's claims 32-36 all ultimately depend from Appellant's independent claim 31 which reads as follows:

Claim 31 A method for quantifying the relative amount of one or more analytes present in a specimen, comprising the steps of:

a. combining said specimen with a known amount of internal reference species (IRS) if the specimen does not already contain one;

b. capturing and isolating at least one of the one or more analytes and said IRS, wherein said capturing and isolating step comprises a substep of combining said IRS containing specimen with an affinity reagent;

c. quantifying the at least one of the one or more analytes in which said quantifying step comprises using only single dimension mass spectrometric analysis to resolve distinct signals for the analyte and said IRS to determine the amount of the captured analytes relative to the IRS.

Appellant's claims 38-48 all ultimately depend from Appellant's independent claim 37 which reads as follows:

Claim 37 A method for quantifying the relative amount of one or more analytes present in a specimen, comprising the steps of:

a. combining said specimen with a plurality of distinctive internal reference species (IRS's) which correspond to the one or more analytes in the specimen in varied and known concentrations, each of the concentrations being chosen to produce a different mass spectrometric response after mass spectrometric immunoassay;

b. capturing and isolating at least one of the one or more analytes and said plurality of IRS's, wherein said capturing and isolating step comprises a substep of combining said plurality of IRS containing specimens with an affinity reagent;

c. quantifying the at least one of the one or more analytes in which said quantifying step comprises using only single dimension mass spectrometric analysis to resolve distinct signals for the analyte and said IRS's to determine the amount of the captured analytes relative to the IRS's.

In the Board's Decision dated January 24, 2008, the Board summarized the prior art relied upon by the Examiner in setting forth the basis of the rejection (Examiner's Answer 4-5) by reciting a number of findings of fact ('FF") (See Board's Decision on Appeal, page 4, last paragraph through top of page 6). Once the scope and contents of the prior art were determined,

the Board identified the differences between the prior art and Appellant's claimed invention in findings of fact numbered 13 through 17 (See Board's Decision on Appeal, page 6, third paragraph through page 7, second paragraph). The following two findings of fact were identified as differences between the prior art and the claimed invention:

"15. Papac does not describe 'c. quantifying' the analyte 'using only single dimension mass spectrometric analysis to resolve distinct signals for the analyte and said IRS to determine the amount of the captured analytes relative to the IRS" as recited in Claim 31."

"17. Gaskell also describes quantifying the amount of analyte using the signals from the analyte and the internal reference standard in mass spectroscopy (FF 11-12; Gaskell, at pp. 459-60; Answer 5), but not 'using only a single dimension mass spectrometric analysis' as recited in step c. of claim 31."

Accordingly, the Board has determined that neither the Papac reference nor the Gaskell reference discloses Appellant's claimed element of using only single dimension mass spectrometric analysis for quantifying the one or more analytes. Therefore, in that neither Papac or Gaskell disclose each and every element of Appellant's claimed invention, it could not have been obvious to one of ordinary skill in the art to combine Papac and Gaskell to arrive at Appellant's claims.

The Board further states that "Appellants have not pointed to any disclosure in Gaskell which would have led a person of ordinary skill not to use an internal standard in Papac's method." The Board also argues that Appellant has not provided any technical reason as to why an internal standard would not work in MALDI/TOF spectroscopy which is the particular spectroscopic method utilized by Papac. However, if one were to use an internal reference standard in the method disclosed by Papac, one would still not arrive at Appellant's claimed invention, and in particular Appellant's claims 35 and 36.

Appealed claim 35 depends from appealed claim 32 which in turn depends from appealed claim 31. Rewriting appealed claim 35 to include all of the limitations of any base claims and any intervening claims results in the following claim:

A method for quantifying the relative amount of one or more analytes present in a specimen, comprising the steps of:

a. combining said specimen with a known amount of internal reference species (IRS) if the specimen does not already contain one;

b. capturing and isolating at least one of the one or more analytes and said IRS, wherein said capturing and isolating step comprises a substep of combining said IRS containing specimen with an affinity reagent and the steps of:

immobilizing at least one antibody onto a solid substrate to produce an affinity reagent;

combining an effective amount of the affinity reagent with the specimen to produce a post-combination affinity reagent and an unbound remainder of the specimen;

separating the post-combination affinity reagent from the unbound remainder of the specimen to form an isolated post-combination affinity reagent;

adding a disassociation agent to the isolated post-combination affinity reagent; and

adding a laser desorption/ionization agent to the isolated post-combination affinity reagent to form a post-combination affinity reagent mass spectrometric mixture;

c. quantifying the at least one of the one or more analytes in which said quantifying step comprises using only single dimension mass spectrometric analysis to resolve distinct signals for the analyte and said IRS to determine the amount of the captured analytes relative to the IRS.

Appealed claim 36 depends from appealed claim 33 which in turn depends from appealed claim 32 which in turn depends from appealed claim 31. Rewriting appealed claim 36 to include all of the limitations of any base claims and any intervening claims results in the following claim:

A method for quantifying the relative amount of one or more analytes present in a specimen, comprising the steps of:

a. combining said specimen with a known amount of internal reference species (IRS) if the specimen does not already contain one;

b. capturing and isolating at least one of the one or more analytes and said IRS, wherein said capturing and isolating step comprises a substep of combining said IRS containing specimen with an affinity reagent and the steps of:

immobilizing at least one antibody onto a solid substrate to produce an affinity reagent;

combining an effective amount of the affinity reagent with the specimen to produce a post-combination affinity reagent and an unbound remainder of the specimen;

separating the post-combination affinity reagent from the unbound remainder of the specimen to form an isolated post-combination affinity reagent;

adding a disassociation agent to the isolated post-combination affinity reagent; and

adding a laser desorption/ionization agent to the isolated post-combination affinity reagent to form a post-combination affinity reagent mass spectrometric mixture;

c. quantifying the at least one of the one or more analytes in which said quantifying step comprises using only single dimension mass spectrometric analysis to resolve distinct signals for the analyte and said IRS to determine the amount of the captured analytes relative to the IRS and

mass spectrometrically analyzing the post combination affinity reagent mass spectrometric mixture to produce a post combination affinity reagent mass spectrum having a mass spectrometric response for the internal reference species located at a unique mass-to-charge ratio of the IRS, and an analyte mass spectrometric response as a unique mass-to-charge ratio of each analyte species thereby detecting the analyte species and no mass spectrometric response corresponding to the mass-to-charge ratio of the analyte species when the specimen contains no detectable amount of the analyte species; and

determining whether the amount of the analyte species present in the sample is greater or less than the known amount of the IRS by comparing the mass spectrometric response for detected analyte species relative to the mass spectrometric response for the IRS.

Appellant previously distinguished the Papac reference from Appellant's claims 35 and 36 by pointing out that the step of capturing and isolating at least one or more analytes in Appellant's claimed invention is performed completely differently than the process described in Papac. In particular, Appellant stated that Papac fails to disclose releasing an isolated analyte species from an antibody and then detecting the presence of the isolated and released analyte species using a mass spectrometer to determine the presence of the analyte species, the identity of the analyte species, and the quantity of the analyte species. (See page 12, first full paragraph of Appellant's Appeal Brief). Instead, Papac discloses removing 1 microliter aliquots of beads containing the analyte from the column and performing MALDI/TOF on the 1 microliter aliquots of beads (See Papac, page 2611, column 2, first and second paragraphs). Unlike Appellant's claims 35 and 36, Papac does not disclose adding a disassociation agent to an isolated post-combination affinity reagent. At best, Papac only discloses adding a laser desorption/ionization agent (identified as a MALDI matrix solution in Papac) (See Papac, page 2611, first column, second full paragraph). Papac does not disclose adding both a disassociation agent and a laser desorption/ionization agent to the isolated post-combination affinity reagent.

Appellant's arguments recited above with reference to appealed claims 35 and 36 are equally applicable to Appellant's appealed claims 40, 42, and 48 and are herein incorporated by reference.

For the above reasons, Appellant contends that Appellant's appealed claims are directed to patentable subject matter.

Dated: 3/24/08

Respectfully submitted,

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